MINUTES OF THE PROFICIENCY TESTING COMMITTEE MEETING DECEMBER 6, 2001

The Proficiency Testing Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Thursday, December 6, 2001 at 9:00 a.m., Eastern Daylight Time (EDT) as part of the Seventh NELAC Interim Meeting in Arlington, VA. The meeting was led by Chairperson Barbara Burmeister of the Wisconsin State Laboratory of Hygiene. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to address items of importance identified in the committee's previously distributed meeting agenda.*

WELCOME AND INTRODUCTION

Barbara Burmeister introduced herself as Chairperson of the Proficiency Testing (PT) Committee and welcomed the participants. The Committee members then introduced themselves.

CHAPTER 2 COMMENT SUMMARY

Marykay Steinman provided a summary of Comments received in reference to Chapter 2. No language changes are proposed as a result of the comments received, but these comments did result in several topics that will be discussed later in the meeting. The comments and questions received and responded to were related to the following topics:

1. Microbiological PT Sample Preparation
2. PT Sample Costs
3. PT Sample Composition and Concentration Ranges
4. Mechanism to Add New Method Codes
5. Analytes with Problematic Acceptance Criteria
6. PCB Congener PT by Method 1668
7. RCRA Water Matrix PT Issue
8. Confusion Surrounding the Reporting of Analytes with the Assigned Value Equal to Zero
9. Interpretation of the Requirement for Passing Two Out of Three PT Studies

ANALYTE/METHOD CODE SOP

Mike Miller reviewed the proposed changes to the Analyte/Method Code SOP. (See attached for complete details.) It was suggested to add the word "recognized" before "Accrediting Authority" in 2.3.a.and add "or" before "by a USEPA program."

PT REPORTING LIMITS

Ms. Steinman informed the participants that a PT subcommittee was formed to develop tables of PT Reporting Limits (PTRL), primarily because labs routinely report low level results when an analyte was not spiked by the PT provider but its presence may be there due to contamination or due to interaction with other analytes that are present in the PT sample. PTRLs were defined as the lowest concentration a laboratory can detect and classify to successfully pass the PT studies. The PTRL

tables were developed to give guidance in reporting to a laboratory that obtained a positive result below the PTRL. Laboratories will report a less than symbol and the PTRL, as listed. The subcommittee found that as with many other NELAP issues, additional comments and concerns surfaced. Tom McAninch gave a presentation on one of those issues, full details of which are given in the attachment. Of the possible solutions recommended for the issue, none have been discussed at length to date. A member of the audience mentioned that PT providers are required by the National Criteria Document to choose concentrations using a random number generator. He also suggested that the Committee reexamine the concentration ranges so that one does not go below the detection limit of the least sensitive method. Another audience member suggested to expand the Field of Testing Table and Acceptance Criteria to take technology into consideration when the field of proficiency testing changes.

CARL KIRCHER'S VERSION OF CHANGES TO CHAPTER 2

Dr. Kircher developed three options for potential changes to the PT frequency requirements of Chapter 2 and proposed these to the NELAP Accrediting Authority Work Group in the last month. His options were presented to the conference without any endorsement from the Accrediting Authorities Work Group, or any NELAC committee. He listed the relative advantages and disadvantages to each option. (See attachment for full details.) The following "Unfinished Actions" are applicable to all options:

1. Change the Table of PT Acceptance Criteria to reflect the Fields of Proficiency Testing as Matrix - Technology/Method - Analyte (instead of Program - Matrix - Analyte).
2. Add acceptance criteria for additional Fields of Proficiency Testing that may be available (e.g., drinking water radiochemistry, non-potable water whole effluent toxicity).
3. Provide clear definition of what technologies are equivalent (e.g., GC with different detectors, MMO-MUG variations).
4. Address the problems or provide a clear list of availability for PT Providers who do and do not provide the complete list of analytes available under NELAC for particular chemical classes (the most glaring omissions appear to be drinking water Aluminum, wastewater Tin and Titanium, wastewater Volatile Organics gases, and soil Metals).
5. Address the problems of authorizing and providing Primary Accrediting Authorities PT results simultaneously with the customer laboratories receiving these PT results.

Dr. Kircher hopes these issues will be addressed in a timely manner, although the tables which are currently posted on the website will have to maintain their structure until the 2001 Standards become effective in 2003. The PT Committee will review in detail the options presented by Dr. Kircher. Discussion was opened to the floor. One comment made was that there is not enough small lab representation in the NELAP program and costs are taking a toll to include these labs. Several attendees favored Option #2, while others favored keeping the Standards as they currently are. Kansas, a NELAP AA, supports Dr. Kircher's position in reducing the cost to small labs. Oregon, a NELAP AA, also recognizes costs to small labs as a problem. However, some non-NELAC states require 2 PTs per year (the current NELAC standard).

EPA PT DATABASE/CRITERIA DOCUMENT REVISION UPDATE

Ms. Burmeister gave an update on the status of the EPA PT Database. A letter had been sent by the NELAC Board of Directors to Henry Longest and James Hanlon, Assistant Administrators of the EPA, asking for the status of the PT database and a mechanism for the PT Committee to make revisions to the Criteria Document. The Board received a letter in response, indicating that the EPA has opted not to continue the PT database, due to the burden placed on resources. Ms. Burmeister stated that NELAC needs to have a PT database which contains all of the solid and hazardous waste analytes in addition to water analytes. Since the current EPA PT database only tracks water analytes, the PT Committee may look to another organization to develop and maintain a PT database that will meet all of the needs of NELAC. A mechanism to revise the Criteria Document is still under discussion and no word as to its outcome has been presented.

ANALYTES WITH PROBLEMATIC ACCEPTANCE CRITERIA

Ms. Burmeister began her presentation by explaining that a letter was sent to PT providers, Accrediting Authorities (AA), and laboratories, asking for analytes that have been "problematic," reasons why they were problematic and data to substantiate the concern. The Committee wanted to identify any analytes that had failure rates that were greater than 20% and less than 1% and other "problematic" PT analytes and the reason for concern. Responses were received from four PT providers, three AA's, and eight labs relating to this subject. Reasons for concern were:

- Problematic concentration range (low limit too low or high limit too high)
- Acceptance criteria produce limits that do not include the assigned value
- Acceptance criteria produce more stringent limits than calibration verification requirements

Ms. Burmeister listed the analytes with failure rates >20% and their comparative failure rates from the EPA PT program. She also showed a table comparing the EPA PT program with the privatized PT program. The passing rates between the two programs were very similar. She then listed the "problematic" analytes from the current WS and WP programs and specific issues of concern from each group

From the PT provider perspective:

- Analytes with failure rates >20% - WS Orthophosphate, Calcium hardness, Cyanide, Boron, Manganese, Mercury, WP Fluoride, Aluminum, Molybdenum

From the AA perspective:

- Acceptance criteria too tight - WS pH
- High concentration limit too high - WS residual free chlorine
- Acceptance criteria produce limits that do not include the assigned value - WP BOD, TSS

From the laboratory perspective:

- Analytes with acceptance criteria more stringent than calibration verification requirements - WS Calcium, Chloride, Manganese, Vanadium, Orthophosphate, Method 524.2 VOCs
- Acceptance criteria produce limits that do not include the assigned value - WP BOD, Alkalinity
- Low concentration limit is below the reporting limit - RCRA Anthracene, Fluorene, 2,4-Dimethylphenol

The PT Committee wants to recalculate all 2000-2001 acceptance criteria from all PT providers and will be requesting study data from all NIST PT providers to evaluate pass/fail rates. This project is

expected to be done before NELAC 8.

PT TESTING LIMITS IN RCRA

Larry Jackson gave a presentation regarding two points reoccurring at PT Committee discussions: one being preparation methods, the other being the appropriate test level for the PT sample relative to the objective of the laboratory. Within the Resource Conservation Recovery Act (RCRA) community, the representation level is the true value of the site, plus or minus the upper concentration level. This is a given throughout the RCRA world. Dr. Jackson then proceeded to mathematically demonstrate what this means to the PT program in support of RCRA. Dr. Jackson asks that any comments be forwarded to him. One of the PT providers who offers solid matrix PT samples has collected sample preparation methodologies and has linked them to an analytical methodology.

Dr. Jackson then opened discussion to the floor. It was suggested to look at internal verification data, making certain one has homogeneity data with which one can determine the statistical significance of any method variability. Also, it was asked as to what is an appropriate pass/fail rate for the acceptance criteria is. It was asked if Dr. Jackson's presentation and analysis was to come up with alternate criteria for scoring PT's based on the prep method. Dr. Jackson responded that it was to determine what the appropriate testing level is to come up with a PT evaluation that is meaningful to the decision maker in RCRA. The attendee felt that the current scoring of the solid and hazardous waste analyte lumps all the prep methods together. It is bothersome to analysts to have a more accurate result that fails the PT. Dr. Jackson explained that this is one of the reasons the PT Committee started looking at this issue because people that are executing very effective recoveries of the target analytes, are failing. Dr. Kircher pointed out that NELAC Standards Appendix D.4.b of Chapter 2 talks about oversight of PT providers. The last sentence reads "The ongoing monitoring criteria to be used by a PTOB/PTPA shall be developed by NELAC." Dr. Kircher asked if NELAC has developed these ongoing monitoring criteria. Ms. Burmeister responded that it has not yet been developed. In which case, Dr. Kircher feels it would be prudent to take some of the material as presented by Dr. Jackson in developing this criteria. Another attendee suggested using gravimetric values generated by the PT providers in monitoring performance of methods. It was suggested that fixed limits work only if everyone does it the same way.

ANALYTE GROUPS

RaeAnn Haynes gave a presentation on the advantages and disadvantages of analyte groups for labs, accrediting authorities, and PT providers. A subcommittee reviewed the 2001 Standards, including matrix- technology/method-analyte/analyte group and concluded from comments received that putting analyte group back into that structure should be reevaluated. In discussions, it was realized that analyte groups are specific to chromatographic methods and organic compounds. Anand Mudambi presented the perspective from the Accrediting Authorities who were still going to regulate by analyte, and there seemed no way to solve the dilemma of not having to track by analyte. A lab can fail a certain percentage of the analyte group, as long as the same analyte is not failed two out of three times. An advantage to a PT provider might be that an analyte group defines what is done on the PT sample more clearly. The AA's felt that if an analyte group failed at less than 80%, two out of three times, then the AA would be forced to decertify that lab for that entire analyte group. From the laboratory perspective, some labs feel that if they fail one analyte out of a group, the lab

will essentially be disqualified for the group, as most labs will not send out for a single analyte within a large group. In summation, it was acknowledged that there was no satisfactory conclusion that would satisfy the requirements of the labs and the AA's regarding analyte groups. Mike Miller wished to clarify that in the Drinking Water Regulations, there is a requirement of an 80% rule, which applies to 20 compounds. An EPA official mentioned that NELAC can be more stringent and require 100% rather than just 80%.

ADJOURNMENT

There being no further business presented for discussion, Ms. Burmeister adjourned the meeting.

ATTACHMENT A

ACTION ITEMS
PROFICIENCY TESTING COMMITTEE MEETING
DECEMBER 6, 2001

Item No.	Action	Date to be Completed
1.	Re-examine concentration ranges of analytes in PT FOT tables.	NELAC 8
2.	Collect PT Study data from PT providers to re-evaluate acceptance criteria and revise accordingly.	NELAC 8
3.	Evaluate the influence of preparation methods on acceptance criteria.	NELAC 8
4.	Work within the new NELAC structure to develop and maintain a PT database.	ASAP
5.	Evaluate "White paper" presented to PT Committee outlining options for future PT frequency requirements.	April, 2002
6.	Develop technology codes for new field of accreditation and field of proficiency testing.	ASAP

ATTACHMENT B

PARTICIPANTS
PROFICIENCY TESTING COMMITTEE MEETING
DECEMBER 06, 2001

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PTRLs/In-House Lab Incompatibilities

Tom McAninch
Environmental Lab Manager
Eastman Chemical Company

In-House Laboratory Calibration Ranges

- Established by permit and/or statutory requirements
- Do not usually extend to the lowest method capability

PTRLs/spiking ranges often well below regulatory limits and permit limits

Impact of Current PTRLs

- Require labs to treat PT samples in a different manner than actual samples (e.g., PT only calibration curves)

- May require different method (e.g., flame AA - ICP vs. graphite furnace - ICP/MS)

Example PTRLs/Statutory Limits

PTRL	Land Disposal	Tox. Charact.
As – 0.054 mg/l	1.4 mg/L	5.0 mg/L
Cr – 0.012 mg/l	2.77 mg/L	5.0 mg/L
Bz – 0.005 mg/l	0.14 mg/L	6.0 mg/L
1,1-DCE – 0.004 mg/l	0.21 mg/L	6.0 mg/L
HCB – 0.005 mg/l	0.055 mg/l	0.13 mg/l

PTRLs/Eastman NPDES Limits

PTRLs	NPDES Permit Limits
Bz – 0.005 mg/L	0.110 mg/L
Clf – 0.007 mg/L	0.047 mg/L
1,2-DCB – 0.005 mg/L	0.124 mg/L
Tol – 0.004 mg/L	0.065 mg/L
PAHs - 0.005 – 0.012 mg/L	0.048 – 0.225 mg/L

Impact of Current PTRLs

- Require labs to treat PT samples in a different manner than actual samples (e.g., PT only calibration curves)

- May require different method (e.g., flame AA - ICP vs. graphite furnace - ICP/MS)

Eastman Volatile Metal Permit Limits

23 Standards for As, Be, Sb, Pb, and Se require ICP/MS

26 Standards for As, Be, Sb, Pb, and Se high enough to use flame AA or ICP

Technology Issues

Technology Required To Meet PTRL	Technology Commonly Employed By Lab
Low Level SW-846 5035	High Level SW-846 5035
ICP/MS or Graphite Furnace	AA or ICP

Labs receive a score of “Not Acceptable” for reporting “<“ for an analyte whose acceptance range extends below the “<“ value but is not zero

Eastman "Not Acceptable" PT Data

Target	Reported, ppb	Assigned, ppb	Range, ppb	PTRL, Ppb
2,4,6-TCP	<20	16.3	7.13-20.4	5
Fluoran	<10	11.3	7.94-13.9	7
HCBD	<9	14	5.32-16.9	5
HCCP	<70	20.5	0-22.8	5

Extent of Problem

- CWA Metal PTRLs – 6 of 24 Analytes
- CWA VOA – 10 of 29
- CWA SVOA – 40 of 54
- RCRA Solids Metals – 5 of 27
- RCRA Solids VOA – 22 of 22
- RCRA Solids SVOA – 51 of 51

For axial ICP and GC/MS calibrated at 0.005 mg/l for VOA and 0.010 mg/L for SVOA

Possible Solutions

- Add 2nd level of PT samples at higher concentrations
- Raise spiking/PTRL levels of current program
- Modify scoring system

Eastman's 3rd Qtr PT results

- 2,4,6-Trichlorophenol reported <20 ppb
  Assigned value – 16.3 ppb
  Acceptance range 7.13-20.4 ppb
  PTRL – 5 ppb
- Fluoranthene reported <10 ppb
  Assigned value – 11.3 ppb
  Acceptance range – 7.94-13.9 ppb
  PTRL – 7 ppb

Ladies and Gentlemen:

As promised during the last AA teleconference, I have prepared for your review and comments the proposed changes to the NELAC Standards for Proficiency Testing (Chapter 2), along with a substantive change summary, and the relative advantages and disadvantages of each option. The purpose of this submittal is to provide a hard-copy exposition of the entire PT suite of problems so the NELAC standing committee will be able to debate them at the Interim Meeting and to present the best solutions for voting at the Annual Meeting.

OPTION #1:
The 2001 version of NELAC Chapter 2 as is, unchanged.

Executive Summary: Scope of Proficiency Testing is redefined and realigned as sample matrix - technology/method - analyte. For each Field of Proficiency Testing where acceptance criteria are available, laboratories accredited or pending accreditation must do PT's "approximately 6 months apart" and must pass two out of the latest three testing rounds attempted.

Unfinished Actions (applicable to all options):
1. Change the Table of PT Acceptance Criteria to reflect the Fields of Proficiency Testing as Matrix - Technology - Analyte (instead of Program - Matrix - Analyte).
2. Add acceptance criteria for additional Fields of Proficiency Testing that may be available (e.g., drinking water radiochemistry, nonpotable water whole effluent toxicity).
3. Provide clear definition of what technologies are equivalent (e.g., GC with different detectors, MMO-MUG variations).
4. Address the problems or provide a clear list of availability for PT Providers who do and do not provide the complete list of analytes available under NELAC for particular chemical classes (the most glaring omissions appear to be drinking water Aluminum, wastewater Tin and Titanium, wastewater Volatile Organics gases, and soil Metals).
5. Address the problems of authorizing and providing Primary Accrediting Authorities PT results simultaneously with the customer laboratories receiving these PT results.

Relative Advantages:
1. The Fields of Proficiency Testing are more harmonized with the Fields of Accreditation, with no more accrediting authority interpretation of how acceptable matrix PT results relates to test methods eligible for accreditation (a prime example is SW-846 method accreditations since laboratories often run these for both aqueous and soil samples).
2. Laboratories must demonstrate proficiency for all technologies/methods accredited, not just one chosen committed method. Conversely, if proficiency cannot be demonstrated for one technology, the laboratory may be able to retain accreditation for the same analyte with the technology in which PT requirements are fulfilled.
3. Regulatory oversight of laboratories extends more completely to all accredited testing methodologies at least twice per year, rather than relying solely on the biannual on-site assessment (and PT's on only one chosen technology).

4. Supplemental requirements (i.e., EPA's annual drinking water PT requirements for each method) are addressed satisfactorily.

Relative Disadvantages:

1. Primary Accrediting Authorities must track PT status for each technology/method, in addition to each available analyte.
2. COST: To do the full suite of Microbiology and Chemistry under NELAC for drinking water, wastewater, and soil matrices, for two PT attempts per year with one technology, the annual cost is approximately $10000 (this includes a huge volume discount for buying the complete set of ampules for WS, WP, and Soil studies). PT providers are currently allowing laboratories to report PT results for multiple technologies in the same testing round for no additional cost in Chemistry; however, this is not true for Microbiology. Thus, the additional cost of Microbiology PT's by technology is $1000 (total $11000). The costs escalate when buying ampules individually for differing times of the year and when remedial PT's need to be run. If acceptance limits for Radiochemistry are adopted by NELAC PT Committee, annual costs increase by almost $6000 (includes all available radionuclides, but laboratories generally do not have more than one accredited technology per analyte here).

OPTION #2:

Laboratories participate and pass PT samples for each available accredited and pending Field of Proficiency Testing every 12 months or less. History must also be maintained of passing two out of latest three testing rounds attempted.

2.4.1 To be accredited initially and to maintain accreditation, a laboratory shall participate in one ~~two~~ single-blind, single-concentration PT study ~~studies~~, where available, per twelve-month period ~~year~~ for each field of proficiency testing for which it seeks or wants to maintain accreditation. Laboratories must obtain PT samples from a PTOB/PTPA-approved PT provider. Each laboratory shall participate in at least one PT study ~~two PT studies~~ for each field of proficiency testing unless a different frequency for a given program is defined in the appendices. Section 2.5 describes the time period in which a laboratory shall analyze the PT samples and report the results. Data and laboratory evaluation criteria are discussed in Sections 2.6 and 2.7 of this chapter.

2.7.2 Initial or Continuing PT Studies

A laboratory seeking to obtain or maintain accreditation shall successfully complete two initial or continuing PT studies for each requested field of proficiency testing within the most recent three rounds attempted. In addition, the laboratory shall successfully complete at least one PT study for each requested field of proficiency testing within a twelve-month period. For a laboratory seeking to obtain accreditation, the most recent three rounds attempted shall have occurred within 18 months of the laboratory's application date. Successful performance is described in Appendix C. When a laboratory has been granted accreditation status, it shall continue to complete PT studies for each field of proficiency testing, maintain a history of at least one acceptable PT study for each field of proficiency testing during a twelve-month period, and maintain a history of at least two acceptable PT studies for each field of proficiency testing out of the most recent three. The twelve-month period for a given field of proficiency testing shall begin each time the laboratory acceptably passes the PT for that field of proficiency testing. For initial accreditation, the laboratory must successfully analyze two sets of PT studies, the analyses to be performed at least 15 calendar days apart from the closing date of one study to the shipment date of another study for

the same field of proficiency testing. For continuing accreditation, completion dates of successive proficiency rounds for a given field of proficiency testing shall be no greater than twelve ~~approximately six~~ months apart. Failure to meet the annual ~~semiannual~~ schedule is regarded as a failure to meet NELAC PT requirements ~~failed study~~.

2.7.3.1 Supplemental PT Studies for Demonstrating Corrective Action

A laboratory that has attained NELAP accreditation is required to maintain acceptable performance in PT studies conducted on an annual ~~a semiannual~~ schedule. If an accredited laboratory fails to maintain a record of passing at least one PT study per twelve-month period, or of passing two out of the most recent three PT studies, it may be subject to loss of accreditation for one or more fields of accreditation in its current scope of accreditation. A laboratory that is out of compliance with this PT requirement may choose to participate in a Supplemental PT Study for Demonstrating Corrective Action. Corrective Action PT samples must meet the following criteria.

<remainder of section unchanged>

2.7.3.2 Supplemental PT Studies for Expanding an Accredited Laboratory's Scope of Accreditation

A laboratory that has attained NELAC accreditation may add fields of accreditation to its current scope of accreditation. As part of the request to expand its scope of accreditation, the laboratory is required to submit to its Primary Accrediting Authority results of participation in two successful PT studies. The laboratory may use the results of a PT study that meets the requirements of either Section 2.7.2 or 2.7.3.1. After the laboratory is granted accreditation for the requested FOT, the laboratory is required to participate in regular annual ~~semiannual~~ PT studies.

2.7.4 Failed Studies and Corrective Action

Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document in its own records and provide to the Primary Accrediting Authority both the investigation and the action taken. If a laboratory fails the only study attempted for a given field of proficiency testing during the twelve-month period or fails two out of the three most recent studies for a given field of proficiency testing, its performance is considered unacceptable under the NELAC PT standard for that field. A laboratory shall then meet the requirements of initial accreditation as described in Section 2.7.2 - Initial or Continuing Accreditation.

2.7.5 Second Failed Study

The PT Provider reports laboratory PT results to the Primary Accrediting Authority at the same time that it reports results to the laboratory. If a laboratory fails the only study attempted during the twelve-month period or fails a second study out of the most recent three, as described in Section 2.7.4, the Primary Accrediting Authority shall take action, pursuant to Chapter Four, within 60 calendar days to determine the accreditation status of all methods for the unacceptable analyte(s) for that technology/method ~~program~~ and matrix.

2.7.6 Scheduling of PT Studies

A Primary Accrediting Authority may specify which months that laboratories within its authority are required to participate in NELAC PT programs. If the Primary Accrediting Authority chooses to specify the months, then it shall adhere to the required annual ~~semiannual~~ schedule. If the Primary Accrediting Authority does not specify the months, then the laboratory shall determine the annual ~~semiannual~~ schedule.

2.7.7 Withdrawal from PT Studies

A laboratory may withdraw from a PT study for an analyte(s) of for the entire study if the laboratory notifies both the PT Provider and the Primary Accrediting Authority before the closing date of the PT study. This does not exempt the laboratory from participating in the annual ~~semiannual~~ schedule.

Relative Advantages:

1. NELAP Accrediting Authorities must still monitor proficiency testing by technologies as well as by analytes, but the workload increase is alleviated somewhat by updating PT information less frequently than every 6 months (every 12 months).
2. Costs to laboratories may be contained, particularly in Microbiology. Prices increase since laboratories must do PT's for each accredited technology, but the increase is balanced by requiring PT's for each available Field less frequently. Laboratories may also be shielded from any increases in costs should PT suppliers remove the benefit of laboratories being able to report and to receive grades for more than one test method per analyte per testing round per matrix.
3. The regimen of passing PT's at least annually still fulfills supplemental requirements (EPA SDWA analytes and technologies) and is consistent with the operating procedures of most accrediting authorities prior to NELAC and prior to EPA's externalization of the WS and WP programs.

Relative Disadvantages:

1. Accrediting Authorities must keep track of two criteria aspects of PT requirements for laboratories, namely the 2-out-of-3 requirement and the every-12-months requirement (NOTE: This is currently the status quo for Accrediting Authorities operating under the 1999 NELAC Standards for SDWA).
2. The New York State Department of Health will be forced into specifying its PT requirements of participation in PT's every testing round (when it issues its PT's every 6 months) as a supplemental NELAC requirement, and it will lessen the stringency of its program from the status it had prior to NELAC.

OPTION #3:

Requires laboratories to pass PT's every 12 months for each accredited and pending available Field of Proficiency Testing, also pass two out of the latest three PT testing round attempts, and perform a PT at least every 6 months for each available accredited or pending Analyte.

2.4.1 To be accredited initially and to maintain accreditation, a laboratory shall participate in one ~~two~~ single-blind, single-concentration PT study ~~studies~~, where available, per twelve-month period ~~year~~ for each field of proficiency testing for which it seeks or wants to maintain accreditation, unless a different frequency for a given program is defined in the appendices. In addition, for each matrix/analyte combination, the frequency of participation must be at least every 6 months. This means that a laboratory accredited for only one method for a specific matrix/analyte combination must participate in two such studies per calendar year for that matrix/analyte combination.. Laboratories must obtain PT samples from a PTOB/PTPA-approved PT provider. ~~Each laboratory shall participate in at least two PT studies for each field of proficiency testing unless a different frequency for a given program is defined in the appendices.~~ Section 2.5 describes the time period in which a laboratory shall analyze the PT samples and report the results. Data and laboratory evaluation criteria are discussed in Sections 2.6 and 2.7 of this chapter.

2.7.2 Initial or Continuing PT Studies

A laboratory seeking to obtain or maintain accreditation shall successfully complete two initial or continuing PT studies for each requested field of proficiency testing within the most recent three rounds attempted. In addition, the laboratory shall successfully complete at least one PT study for each requested field of proficiency testing within a twelve-month period. For a laboratory seeking to obtain accreditation, the most recent three rounds attempted shall have occurred within 18 months of the laboratory's application date. Successful performance is described in Appendix C. When a laboratory has been granted accreditation status, it shall continue to complete PT studies for each field of proficiency testing, maintain a history of at least one acceptable PT study for each field of proficiency testing during a twelve-month period, and maintain a history of at least two acceptable PT studies for each field of proficiency testing out of the most recent three. The twelve-month period for a given field of proficiency testing shall begin each time the laboratory acceptably passes the PT for that field of proficiency testing. For initial accreditation, the laboratory must successfully analyze two sets of PT studies, the analyses to be performed at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing. For continuing accreditation, completion dates of successive proficiency rounds for a given field of proficiency testing shall be no greater than twelve ~~approximately six~~ months apart, and no greater than six months apart for a specific matrix/analyte combination. Failure to meet the annual or semiannual schedule is regarded as a failure to meet NELAC PT requirements ~~failed study~~.

2.7.3.1 Supplemental PT Studies for Demonstrating Corrective Action

A laboratory that has attained NELAP accreditation is required to maintain acceptable performance in PT studies conducted on an annual or semiannual schedule. If an accredited laboratory fails to maintain a record of passing at least one PT study per twelve-month period, or of passing two out of the most recent three PT studies, it may be subject to loss of accreditation for one or more fields of accreditation in its current scope of accreditation. A laboratory that is out of compliance with this PT requirement may choose to participate in a Supplemental PT Study for Demonstrating Corrective Action. Corrective Action PT samples must meet the following criteria.

<remainder of section unchanged>

2.7.3.2 Supplemental PT Studies for Expanding an Accredited Laboratory's Scope of Accreditation

A laboratory that has attained NELAC accreditation may add fields of accreditation to its current scope of accreditation. As part of the request to expand its scope of accreditation, the laboratory is required to submit to its Primary Accrediting Authority results of participation in two successful PT studies. The laboratory may use the results of a PT study that meets the requirements of either Section 2.7.2 or 2.7.3.1. After the laboratory is granted accreditation for the requested FOT, the laboratory is required to participate in regular annual or semiannual PT studies.

2.7.4 Failed Studies and Corrective Action

Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document in its own records and provide to the Primary Accrediting Authority both the investigation and the action taken. If a laboratory fails the only study attempted for a given field of proficiency testing during the twelve-month period or fails two out of the three most recent studies for a given field of proficiency testing, its performance is considered unacceptable under the NELAC PT standard for that field. A laboratory shall then meet

the requirements of initial accreditation as described in Section 2.7.2 - Initial or Continuing Accreditation.

2.7.5 Second Failed Study

The PT Provider reports laboratory PT results to the Primary Accrediting Authority at the same time that it reports results to the laboratory. If a laboratory fails the only study attempted during the twelve-month period or fails a second study out of the most recent three, as described in Section 2.7.4, the Primary Accrediting Authority shall take action, pursuant to Chapter Four, within 60 calendar days to determine the accreditation status of all methods for the unacceptable analyte(s) for that technology/method ~~program~~ and matrix.

2.7.6 Scheduling of PT Studies

A Primary Accrediting Authority may specify which months that laboratories within its authority are required to participate in NELAC PT programs. If the Primary Accrediting Authority chooses to specify the months, then it shall adhere to the required annual ~~semiannual~~ schedule. If the Primary Accrediting Authority does not specify the months, then the laboratory shall determine the annual or semiannual schedule.

2.7.7 Withdrawal from PT Studies

A laboratory may withdraw from a PT study for an analyte(s) of for the entire study if the laboratory notifies both the PT Provider and the Primary Accrediting Authority before the closing date of the PT study. This does not exempt the laboratory from participating in the annual or semiannual schedule.

Relative Advantages:

1. Although less stringent than the PT requirements in the 2001 NELAC Standards, there is no lessening of the rigor of PT requirements than those in the 1999 version of the NELAC Standards or of the PT requirements from the New York State Department of Health prior to NELAC.
2. Laboratories accredited in more than one technology for each sample matrix and analyte may save substantially in the costs of complying with NELAC PT requirements. For laboratories accredited with only one technology per analyte, there is no change effectively in the NELAC PT requirements or in the cost of compliance.

Relative Disadvantages:

1. Accrediting Authorities must now keep track of 2-out-of-the latest-3 PT's for each matrix-technology-analyte combination, passing PT's every 12 months for each matrix-technology-analyte combination, and participating in PT's (not necessarily passing?) every 6 months for each matrix-analyte combination. Note that re-inserting the 6-month requirement for matrix-technology-analyte combinations returns us to the status quo of the 2001 NELAC PT requirements.
2. There may be perceived discrimination in operating an accreditation program, in that laboratories accredited in one technology per analyte must do PT's twice as often per accredited Field of Proficiency Testing compared with laboratories accredited in two technologies per analyte in the same sample matrix.

There you have it! I'm ready for the comments and questions! For my part, I would really like to be able to have all these Fields of Accreditation, Fields of Proficiency Testing, and PT requirements issues all worked out (one way or another) for the 2002 NELAC voting session, and it is my hope that this long

expose of the issues will parameterize and characterize the debates and discussions, as well as facilitate a consensus solution.

Sincerely yours,

Carl Kircher